

EXHIBIT K

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CLAIMS:

1. A liquid pharmaceutical composition for oral administration to a subject in need thereof which comprises a therapeutically effective amount of metformin or its pharmaceutically acceptable salt thereof in association with a pharmaceutically acceptable liquid carrier.

2. The liquid pharmaceutical composition according to claim 1, where the pharmaceutically acceptable carrier is water.

3. The liquid pharmaceutical composition according to claim 1 comprising a therapeutically effective amount of the pharmaceutically acceptable salt of metformin in association with a liquid carrier.

4. The liquid pharmaceutical composition according to claim 3, wherein the pharmaceutically acceptable salt is metformin hydrochloride.

5. The liquid pharmaceutical composition according to claim 3, wherein the pharmaceutically acceptable carrier is water.

6. The liquid pharmaceutical composition according to claim 1 which additionally comprises a sweetener that does not increase the blood glucose level of a subject after ingestion thereof.

7. The liquid pharmaceutical composition according to claim 1 which additionally comprises a sweetener that does not increase the blood glucose

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level of a subject after ingestion thereof, an alkyl hydroxyethylcellulose, or a polyhydroxy alcohol, or combination thereof.

8. A liquid pharmaceutical composition which comprises a therapeutically effective amount of metformin, or its pharmaceutically acceptable salt, a sweetener that does not increase the blood glucose level of a subject after ingestion thereof, an alkyl hydroxyethylcellulose and a polyhydroxy alcohol in association with a pharmaceutically acceptable carrier, said sweetener being present in amounts ranging from about 40% to about 80% by weight, said alkyl hydroxyethylcellulose being present in amounts ranging from about 0.01% to about 5% by weight and said polyhydroxy alcohol being present in amounts ranging from about 5% to about 55% by weight.

9. The pharmaceutical composition of claim 8 wherein the sweetener is present in amounts ranging from about 50% to about 70% by weight.

10. The liquid pharmaceutical composition of claim 9, wherein the sweetener is present in amounts ranging from about 55% to about 65% by weight.

11. The liquid pharmaceutical composition of claim 8, wherein the alkyl hydroxyethylcellulose is present in amounts ranging from about 0.05% to about 1% by weight.

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12. The liquid pharmaceutical composition of claim 11, wherein the alkyl hydroxyethylcellulose is present in amounts ranging from 0.08% to about 0.2% by weight.

13. The liquid pharmaceutical composition of claim 8, wherein the polyhydroxy alcohol is present in amounts ranging from about 15% to about 40% by weight.

14. The liquid pharmaceutical composition of claim 13, wherein the polyhydroxy alcohol is present in amounts ranging from about 20% to about 30% by weight.

15. The liquid pharmaceutical composition of claim 8, wherein the alkyl group in alkyl hydroxy ethyl cellulose contains 2 to 10 carbon atoms.

16. The liquid pharmaceutical composition of claim 8, wherein the sweetener is a sugar alcohol or non-nutritive sweetener.

17. The liquid pharmaceutical composition of claim 8, wherein the polyhydroxy alcohol contains 2 to 6 carbon atoms and contains 2 to 6 hydroxy groups

18. The liquid pharmaceutical composition of claim 8, wherein the polyhydroxy alcohol is a polymer having a molecular weight ranging from 200 to 2000 daltons and has a repeating unit of 2 to 6 carbon atoms and the repeating unit contains 2 to 6 hydroxy groups.

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19. The liquid pharmaceutical composition according to claim 8, wherein the pharmaceutical carrier is water.

20. The liquid pharmaceutical composition according to claim 6 wherein the pH of the formulation ranges from about 4.0 to about 9.0.

21. The liquid pharmaceutical composition according to claim 20 wherein the sweetener is present in an amount ranging from about 10% to about 70%.

22. The liquid pharmaceutical composition according to claim 21 wherein the sweetener is a mixture of a sugar alcohol and a non-nutritive sweetener.

23. The liquid pharmaceutical composition according to claim 6 wherein the sweetener is a mixture of a sugar alcohol and a non-nutritive sweetener.

24. The liquid pharmaceutical composition according to claim 22 or 23 wherein the sugar alcohol is present in an amount ranging from about 10 to about 70% by weight and the nutritive sweetener is present in amounts ranging from about 0.1% to about 0.8% by weight.

25. The liquid pharmaceutical composition according to claim 22 or 23 wherein the sugar alcohol is xylitol.

26. The liquid pharmaceutical composition according to claim 22 or 23 wherein the non-nutritive sweetener is a saccharin salt.

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27. The liquid pharmaceutical composition according to claim 22 or 23 which additionally comprises a mineral acid and a bicarbonate salt both in sufficient amounts to maintain the pH in the range of about 4.0 to about 9.0.

28. The liquid pharmaceutical composition according to claim 27 wherein the mineral acid is hydrochloric acid, nitric acid, or sulfuric acid.

29. The liquid pharmaceutical composition according to claim 28 wherein the mineral acid is hydrochloric acid.

30. The liquid pharmaceutical composition according to claim 20 wherein the pH ranges from about 4.2 to about 7.0.

31. The liquid pharmaceutical composition according to claim 27 wherein the bicarbonate salt is potassium bicarbonate.

32. A liquid pharmaceutical composition comprising a pharmaceutically effective amount of metformin or a salt thereof, a sweetening effective amount of a mixture of xylitol and saccharin or pharmaceutically acceptable salt thereof, and a mineral acid and bicarbonate salt, the acid and bicarbonate salt are present in an amount sufficient so that the pharmaceutical composition has a pH ranging from about 4.0 to about 9.0.

33. The liquid pharmaceutical composition according to claim 1, claim 8 or claim 22, in the form of a liquid suspension.

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34. The liquid pharmaceutical composition according to claim 1 or claim 8 or 22 which additionally comprises an anti-hyperglycemic agent.

35. The liquid pharmaceutical composition according to claim 33, wherein the anti-hyperglycemic agent is glyburide or glipizide.

36. The liquid pharmaceutical composition according to claim 8, in the form of a liquid or a suspension comprising metformin hydrochloride, a non-nutritive sweetener, polyethylene glycol and alkyl hydroxyethylcellulose, wherein alkyl contains 2 to 12 carbon atoms.

37. The liquid pharmaceutical composition according to claim 4, 32 or 36, additionally comprising an anti-hyperglycemic agent.

38. The liquid pharmaceutical composition according to any one of claim 1, 8 or 22 which additionally comprises a flavoring agent, an anti-oxidant, preservative, surfactant, thickener or a chelating agent.

39. The liquid pharmaceutical composition according to claim 38 which additionally comprises an anti-hyperglycemic agent.

40. A method of treating diabetes in a subject in need of treatment comprising administering to said subject an anti-diabetic effective amount of the liquid pharmaceutical composition of any one of claims 1, 8 or 22.

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41. A method of treating hyperglycemia in a subject suffering therefrom which comprises administering to said subject an anti-hyperglycemic effective amount of the liquid pharmaceutical composition of any one of claims 1, 8 or 22.

42. A method for reducing adverse effects of metformin or its pharmaceutically acceptable salt when ingested, which comprises administering to a patient a liquid pharmaceutical composition of any one of claims 1, 8 or 22.

43. A method for facilitating compliance of a patient prescribed to take metformin or its pharmaceutically acceptable salt which comprises administering thereto a pharmaceutically effective amount of the liquid pharmaceutical composition of any one of claims 1, 8 or 22.

44. The liquid pharmaceutical composition according to claim 8 wherein the polyhydric alcohol is a mixture of a first polyethylene glycol having a molecule weight between 200 and 1000 daltons inclusive and a second polyethylene glycol having a molecular weight between 1000 and 2000 dalton, inclusive.

45. The liquid pharmaceutical composition according to claim 44 wherein the weight ratio of the first polyethylene glycol to the second polyethylene glycol ranges from about 1.5:1 to about 4:1.

46. The liquid pharmaceutical composition according to claim 21 wherein the sweetener is present in amounts ranging from about 20% to about 60% by weight.

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47. The liquid pharmaceutical composition according to claim 46 wherein the sweetener is present in amounts ranging from about 30% to about 50% by weight.

48. The liquid composition according to claim 24 wherein the weight ratio of sugar alcohol to non-nutritive sweetener ranges from about 700:1 to about 85:1.

49. The liquid composition according to claim 48 wherein the weight ratio of sugar alcohol to non-nutritive sweetener ranges from about 300:1 to about 100:1.

50. The liquid composition according to claim 48 wherein the weight ratio of sugar alcohol to non-nutritive sweetener ranges from about 200:1 to about 110:1.